

R E M A R K S

Claims 1-5 and 14-18 are pending in the application. Claims 1-5 are rejected under 35 U.S.C. § 112, first paragraph. Claims 14-17 are rejected under 35 U.S.C. § 102(e) and claims 14-18 are rejected under 35 U.S.C. § 103. Applicants have amended the claims to more particularly point out and distinctly claim the invention. Specifically, claim 1 has been amended to delete reference to the S100-AG protein. In addition, claim 14 has been amended to indicate that the kit encompassed by the claim relates to detection of S100 proteins selected from the group consisting of S100-A7, S100-A8 and S100-A9. No new matter is introduced by the amended claims and the claims are fully supported by the instant specification. For reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

1. Compliance with the Sequence Rules

According to the Examiner, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, the application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Specifically, the sequence disclosures that appear on page 15, line 10, and page 17, lines 14 and 15, of the specification must be included in a Sequence Listing.

Applicants submit herewith a Sequence Listing which complies with the requirements for patent applications containing nucleotide sequence or amino acid sequence disclosures.

2. Specification and Claims Objections

The specification is objected to because "Tween™" is misspelled on page 18, line 8. The specification is also objected to because of the improper use of the trademark "TWEEN" on page 18. In response, Applicants have amended the specification to correct the use of the term "TWEEN."

Claims 1-5 and 14-18 are objected to because claims 1 and 14 are drawn in the alternative to the subject matter of non-elected inventions.

Applicants have amended claims 1 and 14 to encompass a method for diagnosis of cancer in a subject, rather than a method for diagnosis and prognosis of cancer in a subject.

3. The Rejections Under 35 U.S.C. § 112

Claims 1-5 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner alleges that the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims are drawn to a method comprising detecting S100-AG, but the specification does not describe S100-AG, or an antibody that binds specifically to S100-AG.

To expedite the allowance of claims, Applicants have amended claim 1 without prejudice to remove the term "S100-AG" in section (a) of the claims.

In view of the foregoing amendment to claims, the rejections under 35 U.S.C. § 112, first paragraph should be withdrawn.

4. The Claims are not Anticipated

Claims 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,150,345-A ("the '345 patent"). The '345 patent is alleged by the Examiner to teach a kit or pre-packaged fluorescently-labeled anti-S100 antibody, which is manufactured by DAKO.

Anticipation requires that all the elements and limitations of the claim be found within a single prior art reference. There must be no difference between the claimed invention and the reference disclosed, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Formulation v. Genetech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Applicants believe, for reasons detailed below, that claims 14-17 are not anticipated by the '345 patent. First, Applicants have amended claim 14 to encompass a kit for diagnosis of cancer, wherein the S100 protein to be detected is selected from the group consisting of S100-A7, S100-A8 and S100-A9. Second, since the '345 patent fails to disclose a kit for detection of the S100-A7, S100-A8 or S100-A9 proteins the '345 patent cannot anticipate the presently claimed invention.

5. The Claims are not Obvious

Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '345 patent in view of Ostergaard (*Cancer Research* 1997 57: 4111-4117; "Ostergaard"). According to the Examiner, the '345 patent teaches a kit or pre-packaged fluorescently-labeled anti-S100 antibody. Although the '345 patent does not teach a kit further comprising a labeled secondary antibody that immunospecifically binds the anti-

S100 antibody, Ostergaard teaches an indirect immunofluorescence assay that uses a rhodamine-labeled secondary antibody that binds specifically to the primary antibody.

The Examiner alleges that in view of the teachings of the '345 patent and Ostergaard, it would have been *prima facie* obvious to one of ordinary skill in the art to manufacture a kit comprising an anti-S100 primary antibody and a rhodamine-labeled secondary antibody that binds the primary antibody. Further, one would have been motivated at the time the invention was made to have done so, because such a kit would obviate the need to label the primary antibody directly.

A finding of obviousness under § 103 requires a determination of the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1 (1966). The relevant inquiry is whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell* 853 F.2d 894 (Fed. Cir. 1988).

The present invention is not rendered obvious by either the '345 patent or Ostergaard either alone, or in combination, for reasons detailed below.

First, as indicated above the '345 patent fails to disclose or suggest a kit for diagnosis of cancer based on detection of S100-A7, S100-A8 or S100-A9 proteins. Second, the disclosure or suggestion, that is absent from the '345 patent is not supplied by Ostergaard. Ostergaard merely discloses the use of indirect immunofluorescence for determining the degree of differentiation of squamous cell carcinomas. Ostergaard fails

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to disclose or suggest anything related to kits designed for detection of the S100-A7, S100-A8 or S100-A9 proteins.

Therefore, claims 14-18 cannot be rendered obvious in view of the '345 patent and Ostergaard.

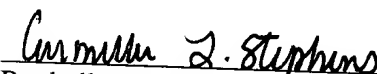
For all the foregoing reasons, the cited references do not render the claims obvious, so that the rejection should be withdrawn.

CONCLUSION

Entry of the foregoing remarks into the file history of the above identified application is respectfully requested. Applicants believe that the invention described and defined by the claims is patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the claims is requested. An early allowance is earnestly sought.

Respectfully submitted,

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